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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,195	10/31/2003	Linda M. Pacioretty	CLANACCR_001NP	4532
John G. Babish Bionexus Limited 30 Brown Road Ithaca, NY 14850				
7590 12/27/2010				
EXAMINER				
CHONG, YONG SOO				
ART UNIT		PAPER NUMBER		
1627				
MAIL DATE		DELIVERY MODE		
12/27/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Interview Summary

**Application No.**

10/699,195

**Applicant(s)**

PACIORETTY ET AL.

**Examiner**

Yong S. Chong

**Art Unit**

1627

All participants (applicant, applicant's representative, PTO personnel):

(1) Yong S. Chong.

(3) \_\_\_\_\_.

(2) Mr. John Babish.

(4) \_\_\_\_\_.

Date of Interview: 21 December 2010.

Type: a) ☒ Telephonic b) ☐ Video Conference

c) ☐ Personal (copy given to: 1) ☐ applicant

2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 21-24, 28, 29, 32-35, 39 and 40.

Identification of prior art discussed: yes.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Yong S. Chong/  
Primary Examiner, Art Unit 1627

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135 (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant argues nonobviousness in the Medford reference as it relates to NF- $\kappa$ B and hyperlipidemia in VCAM-1 expressing cells. Applicant goes into great detail about HUVE/HAEC cell models not synthesizing LDL. This is not persuasive because only the part in the background section of Medford regarding the link between NF- $\kappa$ B and hyperlipidemia, and that NAC is a NF- $\kappa$ B inhibitor, was only used in the rejection. Therefore, the arguments directed to the actual composition and methods taught by Medford and corresponding mechanism of action are basically irrelevant to what it was actually relied on for.

Applicant argues that previously submitted, Kleinveld reference, teaches that NAC acts as a pro-oxidant rather than an anti-oxidant, therefore does not lower LDL levels. Examiner will take a closer look and consider this evidence, however, this may or may not reflect the state of the art as it relates to NAC being used for the claimed methods.

Applicant argues against substituting the antioxidant, Coenzyme Q10 in McCleary, for NAC in Medford because Coenzyme Q10 was not used for its antioxidant properties, but for facilitating respiratory chain function and hence augments the process of reverse electron transport. Examiner will take a closer look and determine that this is not because of the properties of an antioxidant but limited to the Coenzyme Q10.

Applicant argues that McCleary uses not only Coenzyme Q10 but in combination with additional active agents, therefore not attributing the therapeutic effect to only Coenzyme Q10. This is not persuasive because the instant claims use the transitional phrase "comprising" so as to not preclude additional active agents. Examiner suggested the term "consisting of" as an alternative.

Applicant argues unexpected results in the combination of NAC and CLA for the methods of treating hyperlipidemia and lipodystrophy in a HIV infected patient and points to the Declaration filed on 10/27/08. This is not persuasive because of several issues:

- 1) It is not clear if the data is unexpected or not because there is no directed comparison made to NAC alone or CLA alone, therefore it is not certain where the therapeutic activity lies.
- 2) The data is not commensurate with the scope of the claims. The data shows a reduction in LDL levels, however no data is given for treating lipodystrophy. Furthermore, there is no experimental conditions shown, such as dosages, which is not reflected of the instant claims, which also recite no specific dosage ranges.
- 3) Applicant claims that no direct comparison can be made with CLA because it is unethical to administer it to the patient population since it raises LDL levels. This is indirect evidence of unexpected results for the combination of CLA and NAC. This is not persuasive because the facts remain that no comparison is made with the combination of CLA and NAC. Applicant point to Larsen as a review article regarding the effects of CLA. Examiner will take a closer look at this to determine whether it is reflective of the state of the art.

Finally, Examiner reminds Applicant that the instant obviousness rejection could have been formulated in many ways. The one used was for substituting one known antioxidant for another based on their functional equivalence. The other way could have been combining two composition known for the same purpose, which is to treat hyperlipidemia.